EXHIBIT 13

REPORT OF EDWARD J. BUTHUSIEM

Edward J. Buthusiem

May 10, 2019

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I. Introduction and Summary of Opinions

A. Background and Introduction

1. I, Edward J. Buthusiem, Managing Director of Berkeley Research Group, LLC ("BRG"), 1800 M Street NW, Washington, DC 20036, hereby submit this report, which sets forth my opinions in the above-captioned matter.

2. A summary of my Experience and Qualifications is attached as Exhibit 1 to this report. My Curriculum Vitae describing in detail my professional experience, educational credentials, and recent testimony is also found in Exhibit 1.

3. The opinions in this report are my own and are based upon my education, professional experience, the references cited in this report, and examination of the documents, electronic data, and other information provided by the parties in this action. A detailed recitation of my opinions and work performed is discussed throughout the remainder of this report. My opinions are subject to change should I receive additional documents and/or information.

4. The specific materials that I have relied upon to form my opinions are listed in Exhibit 2 to this report.

5. In preparing this report, I have been assisted by staff at BRG, working under my supervision and control. BRG bills for professional services rendered based on actual hours incurred at contractually agreed-upon rates per hour. My billing rate is $750 per hour. BRG's compensation in this matter is not dependent on, or in any way contingent upon, my findings or opinions or the outcome of the litigation.

6. I understand the County of Cuyahoga, Ohio and the County of Summit, Ohio (collectively, "Plaintiffs" or "Counties") have filed complaints against drug manufacturers, distributors, and pharmacies (collectively "Defendants") in the matter captioned IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION. The complaints allege, among other things, that:

    a. "[t]he failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties;"[1]

    b. "Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area;"[2] and

    c. "The massive amount of opioids that flooded into [the Counties] as a result of Defendants' wrongful conduct has devastated the Plaintiffs and their communities."[3]

[1] County of Cuyahoga, OH's Second Am. Corrected Compl. ¶ 466, *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (N.D. Ohio May 30, 2018) (hereinafter "Cuyahoga Compl."); County of Summit, OH's Corrected Second Am. Compl. & Jury Demand ¶ 498, *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (N.D. Ohio May 29, 2018) (hereinafter "Summit Compl.").

[2] Cuyahoga Compl. ¶ 525.e; Summit Compl. ¶ 702.g.

[3] Summit Compl. ¶ 714; *see* Cuyahoga Compl. ¶ 645.

7. In reference to the allegations discussed above, Lacey R. Keller submitted an Expert Analysis report on behalf of Plaintiffs focused "specifically and exclusively on manufacturers' anti-diversion and suspicious order monitoring programs."[4] Ms. Keller was also "asked to trace the orders made by distributors that were deemed peculiar by a manufacturer to the end pharmacy buyer through that manufacturer's chargeback data."[5]

8. In Section M of her report, Ms. Keller purports to identify Mallinckrodt direct sales to distributors which she says can be traced to sales to pharmacies in Summit County and Cuyahoga County. I have been asked by counsel for Mallinckrodt LLC and SpecGx LLC (collectively, "Mallinckrodt") to review this section of Ms. Keller's report and provide my opinions regarding both the assumptions underlying her methodology and the results of her analysis.

B. Summary of Opinions

9. My opinions as more fully discussed herein are as follows:

   a. Plaintiffs and Ms. Keller mischaracterize the purpose of chargebacks and fail to account for limitations of chargeback data.

   b. Ms. Keller fails to account for limitations specific to Mallinckrodt's sales and chargeback data in her analysis.

   c. Ms. Keller's analysis of Mallinckrodt's "peculiar purchases" reflects numerous errors, and her results are incorrect, inflated, and unreliable.

II. Chargebacks and Mallinckrodt Data

A. Plaintiffs and Ms. Keller mischaracterize the purpose of chargebacks and fail to account for limitations of chargeback data.

10. Ms. Keller relies upon manufacturer chargeback data for many of the analyses discussed in her report, including her analysis in which she claims to trace chargebacks associated with sales in Summit and Cuyahoga Counties to Mallinckrodt direct sales that were flagged as peculiar.[6] However, in framing their allegations and conducting her analyses, both the Plaintiffs and Ms. Keller mischaracterize the purpose of chargebacks in the pharmaceutical industry and fail to address the limitations of chargeback data available to Defendants, which would have impacted the ability to use such chargeback information in the manner in which Ms. Keller asserts. Plaintiffs' statement that manufacturer Defendants purchase chargeback data from distributor Defendants in return for discounts to distributors is incorrect. Manufacturers do not "purchase chargeback data;" rather, distributors submit to manufacturers a request for a chargeback payment, which is a financial reconciliation mechanism, as more fully described below. Ms. Keller's statement that the pharmaceutical industry uses chargebacks to "protect distributors against profit loss" is also an inaccurate explanation of chargebacks.[7] Distributors submit chargeback requests to manufacturers in

[4] Expert Analysis of Lacey R. Keller ¶ 22 (hereinafter "Keller Report").

[5] *Id.* ¶ 25.

[6] *See, e.g.*, *id.* §§ M, N.3.

[7] *Id.* ¶ 33.

order to be compensated for the difference between the price that they paid the manufacturer for products and the discounted price at which they sold those products to their customers (*i.e.*, "downstream registrants") based on pricing that the manufacturer makes available to retail buying groups and the distributors' customers. When a distributor submits a chargeback request to a manufacturer, the distributor provides data about its sales to downstream registrants for which it is requesting a chargeback. Plaintiffs' and Ms. Keller's erroneous and imprecise descriptions of the chargeback process obfuscate the complexity of chargebacks and ignore the limitations of chargeback data.

11. The sale and distribution of pharmaceutical products involves a complex supply chain with many participants, including, *inter alia*, manufacturers, distributors, pharmacies, prescribers, and payers. Within the context of this supply chain, the chargeback process facilitates pricing arrangements for entities that do not buy directly from the pharmaceutical manufacturer. After the distributor sells a product to one of its customers, the distributor "charges back" the difference between (a) the price that the distributor originally paid the manufacturer for the product and (b) the price paid by the distributor's customer.[8] The illustration below depicts the flow of product and dollars between the manufacturer, the distributor, and the distributor's customer, and how the chargeback fits into the sales process. In this example, the manufacturer sells product to the distributor at a WAC price of $100. The distributor then sells that product to its pharmacy customer at a contracted price of WAC – 10%, or $90. Since the price that the distributor sells to the pharmacy is $10 less than its acquisition cost from the manufacturer, this transaction is chargeback eligible, and the distributor submits a chargeback of $10 to the manufacturer for compensation.

12. By their very nature, chargebacks involve several limitations that Plaintiffs fail to acknowledge in their allegations and that Ms. Keller fails to address in her analysis.

[8] Letter from K. Harper, Mallinckrodt to U.S. Dep't of Justice, Drug Enforcement Admin. (Nov. 1, 2010) [MNK-T1 0000280621–23]; *see* CONG. BUDGET OFFICE, PRESCRIPTION DRUG PRICING IN THE PRIVATE SECTOR 25 (2007).

a. Distributors submit chargebacks to the manufacturer *after* the distributor's sale to the distributor's customer. By the time the manufacturer is informed of the distributor's chargeback-eligible sale, the distributor's customer is already in possession of the manufacturer's product. The sale from the distributor to the distributor's customer is not under the manufacturer's control; rather, the manufacturer is notified of the sale by the distributor after the fact.

b. Chargebacks provide a manufacturer with post-transaction information regarding only distributor sales that were *chargeback-eligible* (*i.e.*, sales to a *distributor's* customer that are eligible for a discount through a buying group or as part of the distributor's preferred drug program). Any distributor sales of the manufacturer's product that are not part of a pricing arrangement are not reflected in the chargeback data and would not be visible to the manufacturer through chargeback data.

c. Chargebacks provide a manufacturer with post-transaction information regarding distributor sales of *the manufacturer's own product alone*. Manufacturers do not have visibility into a distributor's sales of other manufacturers' products to downstream registrants, including sales of exact substitutes for the manufacturer's product (*i.e.*, multi-source or generic products) through chargeback data. Because it is limited to the manufacturer's products, the chargeback data received by the manufacturer is an incomplete picture of all products and volume purchased by a distributor's customer, and all sales by that distributor.

13. Across the pharmaceutical industry, chargeback requests from distributors to manufacturers do not indicate what specific product inventory (i.e., which particular bottles or packages) the distributor used to fulfill the sale to the downstream registrant. A distributor's inventory is comprised of product purchased over the course of multiple orders placed with the manufacturer. The chargeback data submitted with respect to any eligible distributor-to-downstream registrant sale does not delineate which specific distributor-to-manufacturer order relates to the chargeback. As such, a *manufacturer cannot use chargeback data to trace a downstream sale back to the specific original direct manufacturer-to-distributor sale (or sales)* from which the downstream sale is sourced. Distributors do not report the origin manufacturer-to-distributor sale(s) associated with each downstream sale for which they are requesting a chargeback because (a) there is no business reason to include that information on a chargeback request, and (b) doing so would overcomplicate the already voluminous chargeback data submitted to the manufacturer. These points are discussed in greater detail below.

14. The basic information accompanying a chargeback request includes: the distributor's name and address; the distributor's customer's name and address; the date of the sale; the product (*i.e.*, NDC) sold; the quantity sold; the price paid by the distributor's customer; the contract governing the customer's price; and the amount of the chargeback invoiced by the distributor to the manufacturer pursuant to its distribution agreement with the manufacturer. These are the key pieces of information that the manufacturer needs to verify the downstream sale in order to compensate the distributor for the difference in price paid versus price sold. The manufacturer does not need to know which original purchases by the distributor contributed to the inventory that the distributor sold to a downstream registrant in order to process or pay the chargeback; after all, the manufacturer has a record of all of the distributor's direct purchases. Manufacturers use their direct sales data in conjunction with other analytical processes to ensure that distributors are not submitting chargeback claims for inventory

that was not originally purchased from the manufacturer. For example, if a distributor submits a chargeback to a manufacturer for an NDC that the manufacturer never sold to that distributor, the manufacturer will deny the chargeback request.

15. Moreover, as I note in Paragraph 13, distributors may fulfill any one downstream sale with inventory purchased through one or more orders from the manufacturer over a period of time. If manufacturers required distributors to reference the original purchase or purchases to which each downstream sale was sourced, each chargeback transaction could reflect a different number of "original order" data fields as a result. This would complicate the standard electronic data transfer between manufacturers and distributors. This is not how the chargeback process works.

16. Despite the foregoing, in her report, Ms. Keller attempts to perform a number of analyses that rely on manufacturer chargeback data. She does not address the limitations inherent in chargeback data or how these limitations impact her findings and any conclusions that may be drawn from her analysis.

B. Ms. Keller fails to account for limitations specific to Mallinckrodt's sales and chargeback data in her analysis.

17. In Section M of her report, Ms. Keller performs an analysis that purports to "trace" chargebacks related to pharmacy purchases in Cuyahoga and Summit Counties to distributor sales that were flagged as "peculiar" by Mallinckrodt, and states that "[w]ith chargeback data, Mallinckrodt was able to see where peculiar orders went." As I discuss in detail below, Ms. Keller's analysis ignores the general limitations applicable to all chargeback data, as discussed above, as well as the specific limitations relevant to Mallinckrodt's chargeback data, the result of which adversely impacted her analysis and rendered it unreliable.

18. I reviewed the direct sales data and chargeback data produced by Mallinckrodt in this matter and confirmed that there is (a) no information submitted by the distributor on the chargeback request indicating the direct manufacturer-to-distributor sale(s) from which the chargeback inventory was sourced, and (b) no way to accurately link, or trace, a chargeback to a direct sale.[9]

19. Ms. Keller's discussion surrounding her chargeback analyses suggests that with chargeback data, Mallinckrodt had nearly complete visibility into sales to downstream registrants – however, she has not verified this assumption. A significant portion of Mallinckrodt's opioid sales were made directly to retail, institutional, and other customers where no chargeback was generated.[10] Absent a chargeback, Mallinckrodt did not have information regarding the location of the specific store or pharmacy that received its products.

20. As Exhibit 5 illustrates, from 1998 through 2017, over 31% of Mallinckrodt's *total* sales of opioids were made directly to retail customers instead of to distributors or wholesaler customers.[11] In fact,

[9] Mallinckrodt Direct Sales Transactions (1998 to 2017) [MNK-TI_0007897646]; Mallinckrodt Chargeback Transactions (1998 to 2017) [MNK-T1_0007965587–88]. The data elements included in Mallinckrodt's direct sales and chargeback data, along with sample data records, are listed in Exhibits 3 and 4.

[10] *Id.*

[11] *Id.*

Mallinckrodt's direct sales to retail customers accounted for 41.4% of the total purchases of Mallinckrodt's opioid products by customers in the *retail* class of trade (*e.g.*, pharmacies).[12] Importantly, these direct sales cannot generate a chargeback because the sales did not go through a distributor. Furthermore, the vast majority of the Mallinckrodt direct sales to retail customers were shipped to pharmacy warehouses around the country and did not include granular information on specific store locations. This is because most of the direct retail sales were made to large retail chains (*e.g.*, CVS, Walgreen, Rite Aid, Walmart, Albertsons), and were shipped to the chains' distribution centers, not individual stores.[13] As such, Mallinckrodt had no visibility regarding the location of specific pharmacies or the geographies associated with over 40% of its retail opioid sales for which no chargeback was available.[14]

21. For specific retail chains, the overwhelming majority of the Mallinckrodt opioid purchases were direct, and the only shipment details provided to Mallinckrodt for these direct purchases were addresses of the companies' distribution centers. For example, 70.1% of Walgreens' purchases and 97.9% of Walmart's purchases were direct, respectively.[15] For these customers, Mallinckrodt did not receive a chargeback request and had no information on the stores or geographies to which its products were being distributed. However, in performing her analyses and reaching conclusions regarding suspicious orders, Ms. Keller fails to address or even acknowledge the limited information Mallinckrodt had regarding a significant portion of its retail sales.

III. Ms. Keller's analysis of Mallinckrodt's "peculiar purchases" reflects numerous errors, and her results are incorrect, inflated, and unreliable.

22. In her analysis entitled "Downstream Customers of Suspicious Orders," Ms. Keller states: "I was directed by counsel to determine if I could trace the purchase by buyers located in Summit or Cuyahoga counties of a particular NDC product, bought around the time Mallinckrodt deemed the order peculiar. Mallinckrodt also produced chargeback data that contained information regarding purchases by pharmacies and other end buyers. I used this data to identify Summit and Cuyahoga buyers that purchased an opioid product from a distributor within three days (before or after) of that distributor being deemed peculiar by Mallinckrodt for a transaction involving that same opioid."

23. As discussed above, there is no way to trace a chargeback to the distributor's original purchase from the manufacturer. Even assuming, *arguendo*, that her analysis is not fundamentally flawed in that regard, however, Ms. Keller's results are nonetheless incorrect, overstated and unreliable because she employs unsupported assumptions and incorrectly applies her own methodology.

A. Ms. Keller incorrectly executes her own methodology.

24. First, Ms. Keller incorrectly applies her own methodology through a mistake in her code. Based on the description in her report and the supporting code she produced, it appears that Ms. Keller

[12] *Id.*

[13] These five retail chain pharmacies account for over 83% of Mallinckrodt's direct sales to retail customers.

[14] *See* Ex. 6 for a summary of retail customer purchases of Mallinckrodt opioids.

[15] *See* Exs. 7–8 for a summary of Walgreens and Walmart purchases of Mallinckrodt opioids.

attempted to link chargeback requests submitted to Mallinckrodt by distributors for sales to pharmacies in Summit or Cuyahoga to peculiar direct sales transactions involving those same distributors and the same opioid product on the chargeback.[16] To implement her logic, Ms. Keller should have precisely matched (1) the distributor on the chargeback to the distributor on the peculiar order, (2) the product on the chargeback to the product on the peculiar order by NDC code, and (3) the date on the chargeback to within 30 days after the date on the peculiar order. Figure 1 below illustrates an example of the correct implementation of Ms. Keller's "tracing" logic in which she matched all three of these elements; namely, "Ship To" Number (Wholesaler ID), Invoice Date, and NDC.

Figure 1: Selected Mallinckrodt Order Flagged as Peculiar and Corresponding Mallinckrodt Chargeback Record for Summit / Cuyahoga Buyer within 30 Days as Traced by Ms. Keller

Mallinckrodt Peculiar Order	
Ship To Name	AMERISOURCEBERGEN DRUG CORP
Ship To Number	52000306
Order Number	70162282
Invoice Date	3/11/2010
NDC	00406833001
Quantity Shipped	120

Mallinckrodt Chargeback Record	
Wholesaler Name	AMERISOURCEBERGEN DRUG CORP
Wholesaler ID	52000306
Order Number	19972483
Invoice Date	3/12/2010
NDC	00406833001
Quantity Ordered	12
Ship To Name	Cleveland Clinic Pharmacy
Ship To County	Cuyahoga
Ship To State	OH

25. In the first step of her analysis, Ms. Keller successfully executed her logic matching the elements of the Summit and Cuyahoga chargebacks with elements of the peculiar orders to identify what she deems *potentially* related chargebacks. However, when Ms. Keller summarized the peculiar orders related to the Counties' chargebacks to create Table 74 of her report, she did not accurately compare across the data files and thus inflated the number of peculiar orders included in Table 74. Rather than matching across *all* three of the key data elements for each peculiar order and a specific chargeback, Ms. Keller's code compares individual data elements in succession. As such, she includes a peculiar order in Table 74 if only some, but not all three, of the key elements on that order are found on any of the traced chargebacks.

26. For example, the distributor's Ship To Number may match to one chargeback while the Invoice Date and NDC match to completely different chargebacks.[17] This error in her code caused Ms. Keller to include 832 peculiar transactions in Table 74 that cannot be associated with a chargeback in Summit or Cuyahoga Counties— even under her own flawed methodology. The example reflected in Figure 2 below illustrates the error in Ms. Keller's process whereby she did not correctly match all three of the elements necessary to "trace" the chargebacks to Mallinckrodt direct sales.[18] Figure 2

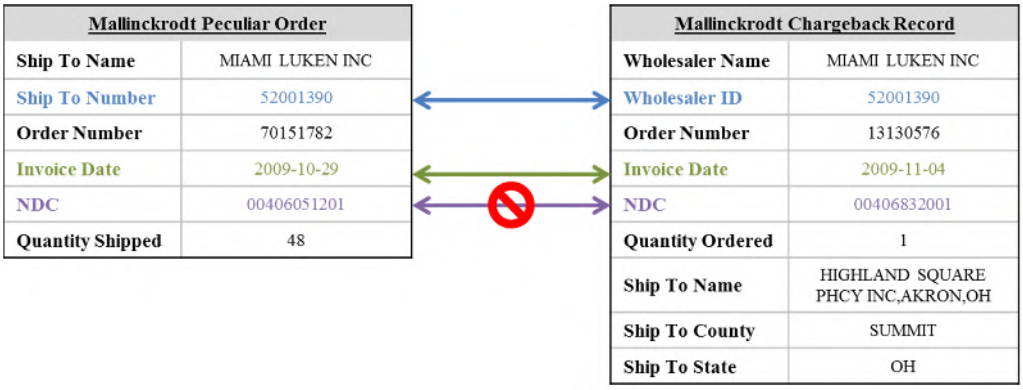
[16] Keller Report ¶¶ 156, 158. *mallinckrodt_sors_analysis.sql*.

[17] Keller Report, *mallinckrodt_sors_analysis.sql* lines 105–15. In addition to Ship To Number, Invoice Date, and NDC, Ms. Keller also uses Ship To Name, Sold To Name, ARCOS Name, and Order Number when linking the traced chargebacks back to the peculiar orders.

[18] The error in Ms. Keller's code is presented in Exhibit 9.

demonstrates that she incorrectly applied only two of the three key tracing elements and, as a result, matched a chargeback to an order for product with a different NDC code.

Figure 2: Selected Mallinckrodt Order Flagged as Peculiar and Corresponding Mallinckrodt Chargeback Record for Summit / Cuyahoga Buyer within 30 Days as Traced by Ms. Keller; NDC Does Not Match



Mallinckrodt Peculiar Order	
Ship To Name	MIAMI LUKEN INC
Ship To Number	52001390
Order Number	70151782
Invoice Date	2009-10-29
NDC	00406051201
Quantity Shipped	48

Mallinckrodt Chargeback Record	
Wholesaler Name	MIAMI LUKEN INC
Wholesaler ID	52001390
Order Number	13130576
Invoice Date	2009-11-04
NDC	00406832001
Quantity Ordered	1
Ship To Name	HIGHLAND SQUARE PHCY INC,AKRON,OH
Ship To County	SUMMIT
Ship To State	OH

27. The peculiar order detailed above is erroneously included in Ms. Keller's Table 74 because she identified chargebacks potentially related to other peculiar orders that are associated with the same NDCs. The full impact of her error (i.e., inclusion of an extra 832 transactions in her Table 74) is summarized in Figure 4 below.

B. Ms. Keller arbitrarily selects a 30-day window for her analysis.

28. Second, Ms. Keller states in Paragraph 156 that she used the Mallinckrodt chargeback "data to identify Summit and Cuyahoga buyers that purchased an opioid product from a distributor within three days (before or after) of that distributor being deemed peculiar by Mallinckrodt." Then, in Paragraph 158, she states that she "identified around 2,900 [peculiar transactions] that involved distributors that shipped the same opioid product purchased in the peculiar transaction to buyers in either Summit County or Cuyahoga County within 30 days." Despite the conflicting day ranges in the text of her report, review of her code confirms that she included chargebacks associated with Summit or Cuyahoga buyers *up to 30 days after* the date of the "peculiar transaction" between Mallinckrodt and the distributor.[19]

29. However, Ms. Keller provides no support or justification for why thirty days is a reasonable period to use for her chargeback "tracing" analysis. Distributors' contracts with manufacturers require that they maintain specific inventory levels and move inventory in a timely manner to avoid product spoilage and expiration.[20] In fact, distribution agreements penalize distributors for stockpiling product and exceeding inventory thresholds through reductions in fees and price appreciation credits.[21] Most

[19] Keller Report, *mallinckrodt_sors_analysis.sql* lines 82, 100.

[20] Hui Zhao et al., *Fee-for-Service Contracts in Pharmaceutical Distribution Supply Chains: Design, Analysis, and Management*, 14 J. MFG. & SERV. OPERATIONS MGMT. 685, App. A-5.2 (2012); Leroy B. Schwartz & Hui Zhao, *The Unexpected Impact of Information Sharing on US Pharmaceutical Supply Chains*, 41 INFORMS 354, 357 (2011).

[21] Zhao et al., *supra* n. 16 at App. A-5.2.

agreements encourage distributors to maintain inventory levels of between two and four weeks,[22] and in my experience, distributors manage their inventories closer to the low end of that range, particularly with regard to inventory of controlled substances. Because her use of a 30-day window exceeds wholesaler inventory management norms, Ms. Keller identifies chargebacks in the two counties that are unlikely to have been sourced to distributor purchases up to four weeks earlier. Had Ms. Keller performed her analysis using a threshold of fourteen days, her results would have been lower by 42.3%. The impact of this alternative 14-day window is summarized in Figure 5 below.

C. Ms. Keller ignores other non-peculiar sales to the same distributors that could have been the source of the chargebacks involving sales to pharmacies in the Counties.

30. Third, and related to the discussion above regarding a manufacturer's inability to trace a downstream transaction in the chargeback data to any particular direct sale, Ms. Keller ignores the multitude of other non-peculiar sales Mallinckrodt made to the relevant distributors that could also have been the source of inventory for the chargebacks associated with buyers in Summit and Cuyahoga counties. Applying Ms. Keller's logic, I find that the Summit County and Cuyahoga County downstream transactions that she "traces" to 858 of the manufacturer-to-distributor transactions flagged as peculiar could just as well have been "traced" to other sales to those same distributors that were not flagged as peculiar transactions by Mallinckrodt. The example reflected in Figure 3 below illustrates this error in her methodology and assumptions. Specifically, this example demonstrates that Ms. Keller "traced" the chargeback data related to the Cuyahoga County pharmacy sale (shown in the middle box) to one peculiar order involving the same distributor and NDC (box on the left). However, she ignored the *two non-peculiar* orders by that same distributor for the same NDC within 30 days (box on the right), that could have been the source of the inventory the distributor sold to the pharmacy in Ohio.

Figure 3: Additional Non-Peculiar Orders Within 30 Days of Summit / Cuyahoga Chargeback Ms. Keller Traces to a Peculiar Order

Mallinckrodt Peculiar Order	
Ship To Name	VALUE DRUG COMPANY
Ship To Number	719578
Order Number	70418591
Invoice Date	4/3/2017
NDC	00406800330
Quantity Shipped	96
Flagged as Peculiar	Yes

Mallinckrodt Chargeback Record	
Wholesaler Name	VALUE DRUG COMPANY
Wholesaler ID	719578
Order Number	44321895
Invoice Date	4/4/2017
NDC	00406800330
Quantity Ordered	18
Ship To Name	AccuScripts Pharmacy LLC
Ship To County	Cuyahoga
Ship To State	OH

Non-Peculiar Mallinckrodt Orders		
Ship To Name	VALUE DRUG COMPANY	
Ship To Number	719578	
Order Number	70416745	70417519
Invoice Date	3/16/2017	3/22/2017
NDC	00406800330	
Quantity Shipped	96	30
Flagged as Peculiar	No	No

[22] *Id.*; Schwartz & Zhao, *supra* n. 16 at 358, Fig. 3; Kathleen Iacocca & Yao Zhao, *Resell vs. Direct Models: US Branded Drug Distribution in the Future*, PHARMEXEC (July 17, 2015), *available at* http://www.pharmexec.com/resell-vs-direct-models-us-branded-drug-distribution-future.

D. The impact of errors on the results of Ms. Keller flawed methodology are significant.

31. The aggregate impact of correcting Ms. Keller's own methodology reduces her finding of 2,860 "Peculiar Orders Traced to Summit and Cuyahoga" by 29.1% to 2,028 orders. Further, accounting for non-peculiar orders in her analysis reduces her findings by an additional 30% to 1,170 orders.

Figure 4: Replication of Ms. Keller's Table 74, Corrected Logic and Adjusted to Account for Non-Peculiar Orders

		# of Peculiar Orders Traced to Summit / Cuyahoga		
Reporter DEA No	Ship to Distribution Center (ARCOS Name and Location)	Ms. Keller's Analysis	Correct Linking Error	Account for Non-Peculiar Sales
RA0314562	AMERISOURCEBERGEN DRUG CORP - LOCKBOURNE, OH	1,039	960	502
RK0236403	KEYSOURCE MEDICAL, INC - CINCINNATI, OH	673	492	374
RH0347282	H. D. SMITH - LOUISVILLE, KY	338	161	85
RA0287020	TEVA PHARMACEUTICALS - GROVEPORT, OH	200	75	40
PP0031904	PRESCRIPTION SUPPLY INC - NORTHWOOD, OH	164	96	34
RB0363630	AMERISOURCEBERGEN DRUG CORP - NORTH AMITYVILLE, NY	109	38	20
PM0031550	MIAMI-LUKEN - SPRINGBORO, OH	106	43	22
RV0464646	VALUE DRUG COMPANY - DUNCANSVILLE, PA	70	23	13
RM0258601	MCKESSON CORPORATION - NEW CASTLE, PA	52	43	41
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Other Distribution Centers	83	75	18
	Total	[redacted]	[redacted]	[redacted]

32. Altering her arbitrary selection of a 30-day window to a 14-day window reduces her finding of 2,860 "Peculiar Orders Traced to Summit and Cuyahoga" by 42.3% to just 1,650 orders. Further, accounting for non-peculiar orders in her analysis reduces her findings by an additional 14.2% to 1,245 orders.

Figure 5: Replication of Ms. Keller's Table 74, Adjusted to Use 14 Day Threshold and Account for Non-Peculiar Orders

		# of Peculiar Orders Traced to Summit / Cuyahoga		
Reporter DEA No	Ship to Distribution Center (ARCOS Name and Location)	Ms. Keller's Analysis	Use 14 Day Threshold	Account for Non-Peculiar Sales (14 days)
RA0314562	AMERISOURCEBERGEN DRUG CORP - LOCKBOURNE, OH	1,039	868	619
RK0236403	KEYSOURCE MEDICAL, INC - CINCINNATI, OH	673	388	341
RH0347282	H. D. SMITH - LOUISVILLE, KY	338	111	77
RA0287020	TEVA PHARMACEUTICALS - GROVEPORT, OH	200	45	28
PP0031904	PRESCRIPTION SUPPLY INC - NORTHWOOD, OH	164	57	36
RB0363630	AMERISOURCEBERGEN DRUG CORP - NORTH AMITYVILLE, NY	109	28	18
PM0031550	MIAMI-LUKEN - SPRINGBORO, OH	106	24	22
RV0464646	VALUE DRUG COMPANY - DUNCANSVILLE, PA	70	23	16
RM0258601	MCKESSON CORPORATION - NEW CASTLE, PA	52	39	38
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Other Distribution Centers	83	49	33
	Total	[redacted]	[redacted]	[redacted]

33. The corrections to Ms. Keller's flawed assumptions and methodology are summarized in Figure 6 below. For the reasons stated above, I disagree with the premise and assumptions underlying Ms. Keller's analysis. However, even adjusting her flawed logic reduces the peculiar orders she incorrectly traces to sales in the Counties by 56% to 60%.

Figure 6: Summary of Corrections and Adjustments to Ms. Keller's Table 74

	# of Peculiar Orders	% National Orders	Total Sales	% National Sales
All Peculiar Orders for Opioid Products	***58,581***	***100.0%***	***$1,636,012,729***	***100.0%***
Peculiar Orders Traced to Summit / Cuyahoga Chargebacks				
Ms. Keller's Results	2,860	4.9%	67,272,632	4.1%
Correct Linking Error	2,028	3.5%	46,874,812	2.9%
Account for Non-Peculiar Sales	1,170	2.0%	25,766,465	1.6%
Use 14 Day Threshold	1,650	2.8%	33,405,802	2.0%
Account for Non-Peculiar Sales (14 days)	1,245	2.1%	26,642,241	1.6%

EXHIBIT 1

QUALIFICATIONS AND EXPERIENCE, BUTHUSIEM CV

34. I am a Managing Director in the BRG Health Analytics practice. I have over 30 years of experience advising clients on a variety of business, regulatory, and transactional matters. Since joining BRG in 2013, I have provided expert testimony and support in numerous disputes and investigations involving, among other things, the interpretation of commercial agreements, as well as deal structures, valuation, fiduciary responsibilities, securities disclosure, and adequacy of internal controls.

35. Prior to joining BRG, from 2010 to 2013, I served as General Counsel, Chief Compliance Officer, and Head of Business Development of KaVo Kerr Group ("KKG"), Danaher Corporation's $4 billion global dental and medical device business. My responsibilities included managing the business development group, which was responsible for the evaluation of strategic technologies and drafting and negotiating scientific and commercial agreements supporting the business. I was also responsible for managing the Legal, Intellectual Property, Compliance, Trade Operations, and Environmental Health and Safety Departments in over 77 countries throughout the world, including China, Vietnam, Japan, Singapore, Malaysia, South Korea, and Hong Kong.

36. Prior to joining KKG, I was an attorney and business development executive at GlaxoSmithKline ("GSK") from 1990 to 2010. GSK is a $45 billion global pharmaceutical and consumer healthcare company. During my tenure at GSK, I served in various senior capacities, including Vice President Global and Strategic Transactions (1994–2000), Senior Vice President, General Counsel, and Head of Deal Structuring for Pharmaceutical R&D, General Counsel and Head of Business Development of GSK's Vaccines Division (from 2000–2008), and Senior Vice President & Special Counsel (from 2008–2010).

37. I was also a member of GSK's R&D Executive Team, the C-Suite team responsible for the overall management of the $6 billion R&D and Vaccines Divisions. I also chaired GSK's Compliance Committee and served as a member of the R&D Scientific Advisory Board, which was responsible for overseeing GSK's scientific technology platforms and experimental products, as well as the GSK Product Review Board, which was the senior committee in GSK responsible for approving all major R&D and commercial agreements, as well as drug development projects as they move from pre-clinical to clinical testing up through and including regulatory approval and launch.

38. While in these positions, I oversaw a team of more than fifty legal and commercial executives and was responsible for negotiating and structuring global commercial transactions for a $6 billion global research and development enterprise within R&D, as well as a $4 billion global vaccine business, with R&D and commercial centers in over twenty countries, including seven in the U.S., as well as in China, Japan, Vietnam, India, and Singapore. During the course of my career, I have drafted, negotiated, and structured hundreds of agreements, including product and R&D licensing and development transactions, co-promotion and co-marketing alliances, supply, manufacturing and distribution agreements, product and business divestitures, and a variety of other commercial and scientific agreements to support these businesses on a global basis. Altogether, I have acted as the lead business development executive and/or managed the support for well over a thousand transactions, involving billions of dollars of value. I was also responsible for providing legal and

operational support to numerous functional areas within GSK, including trade operations, government accounts, managed markets and manufacturing supply and logistics.

39. During the course of my career at GSK, I was involved in providing regulatory and BD support for a number of marketed and developmental products in the pain and pain-related space. For example, in 2002, I drafted and negotiated a Joint Development and Commercialization agreement with Adolor Pharmaceuticals to develop and commercialize Entereg, a drug indicated to treat post-operative constipation in a hospital setting. At BRG, I have advised a number of companies that manufacture opioids and products that are intended to mitigate the adverse effects of opioids.

40. I frequently write and lecture on emerging issues impacting the pharmaceutical and medical device industries on topics related to regulatory and legal compliance, manufacturing and development, corporate governance, government enforcement, and sales and marketing practices.

41. Finally, I am an Adjunct Professor of Law at the Temple University Beasley School of Law. Since Fall 2015, I have taught Introduction to Compliance and Ethics Law, a course that examines the interplay of corporate legal compliance and business ethics in the context of issues arising within the life sciences industry.

EDWARD J. BUTHUSIEM

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SUMMARY

Mr. Buthusiem is a Managing Director in the BRG Health Analytics practice and a leader of its Corporate Compliance and Risk Management practice. He has over 30 years of experience advising clients on a variety of business, regulatory, operational, intellectual property, litigation, transactional and compliance matters, with particular emphasis in pharmaceutical and medical device product and technology licensing transactions, commercial and strategic transactions, business formation and planning, securities, mergers and acquisitions, compliance, and corporate governance. Since joining BRG in 2013, Mr. Buthusiem has provided expert testimony and support in a number of litigation matters involving, among other things, the interpretation of licensing and development contracts relating to pharmaceutical and medical device product development, deal structures, valuation and pricing, matters involving fiduciary responsibilities, securities disclosure, adequacy of internal controls and pharmaceutical pre-clinical and clinical development and commercialization.

Mr. Buthusiem has served as a government and court-appointed monitor for entities subject to post-settlement and post-acquisition mandates, including on behalf of the US Department of Justice (DOJ), the Securities and Exchange Commission (SEC) and the Office of Inspector General (OIG) in connection with various civil and criminal actions. Mr. Buthusiem has also served as a court-appointed monitor in connection with the disposition of assets in bankruptcy proceedings as well as an independent third party to oversee the implementation of post-closing obligations primarily involving M&A transactions. He has advised healthcare companies and their legal counsel in implementing Corporate Integrity Agreements (CIAs), as well as negotiating CIA terms with the Department of Justice, the OIG, the SEC, and other governmental agencies. Mr. Buthusiem has also developed and overseen all aspects of compliance programs, including auditing and monitoring; interactions and engagements with healthcare professionals; determining fair market value of goods and services provided by and offered to physicians; strategic marketing and sales initiatives; transparency reporting; and clinical, research and development, and post-market surveillance.

Prior to joining BRG, Mr. Buthusiem served as General Counsel and Head of Business Development for KaVo Kerr Group ("KKG"), Danaher Corporation's $2.5 billion global dental and medical device business, from 2010 to 2012. His responsibilities included heading the Business Development, Legal, Compliance, Trade Operations and Environmental Health and Safety Departments and overseeing the provision of these services to KKG's global businesses.

Prior to joining KKG, Mr. Buthusiem was a senior executive at GlaxoSmithKline ("GSK") from 1990 to 2010. GSK is a $45 Billion global pharmaceutical and consumer healthcare company. During my tenure at GSK, Mr. Buthusiem served in various senior capacities, including Vice President Global and Strategic Transactions (1994-2000), Senior Vice President & General Counsel of R&D and Vaccines (from 2000-2008) and Senior Vice President & Special Counsel (from 2008-2010). Among other things, Mr. Buthusiem was responsible for managing the team that drafted and negotiated product and technology licensing agreements on a global basis and head of Business Development for the Vaccines Division. Mr. Buthusiem also served as a member on numerous project and product management teams which were responsible for the discovery and development of new drugs and the lifecycle management of existing products and therapeutic franchises.

Prior to joining GSK, Mr. Buthusiem was an attorney in private practice with two nationally recognized law firms, Fried, Frank, Harris, Shriver & Jacobson LLP (from 1984-1988) and Dickstein Shapiro LLP (from 1988-1990). During his tenure in private practice, he worked in both firms' Corporate and Securities practices, and provided legal advice in areas including, but not limited to M&A due diligence and transactions, as well as corporate agreement transactional drafting, guidance, and review.

During his tenure at GSK and KKG, Mr. Buthusiem was responsible for directly drafting and negotiating, as well as managing the support for all global transactions, including mergers and acquisitions, joint ventures, pharmaceutical product and R&D licensing and development transactions, pharmaceutical product divestitures, investment banker and broker deals, venture capital partnerships, academic and scientific collaborations, commercial joint ventures, marketing, supply and distribution agreements and a variety of other corporate and commercial transactions. Altogether, Mr. Buthusiem has acted as 'first chair' and/or managed the support for well over a thousand pharmaceutical and medical device transactions, involving billions of dollars of value. Mr. Buthusiem's expertise includes, but is not limited to the following types of transactions:

- Product and technology licensing and research collaboration agreements
- Research consortia agreements
- Intellectual property in-licensing, out-licensing, and cross-licensing agreements involving pharmaceutical and medical device products and projects
- Drug, device, vaccine, and biological product research and development agreements
- Mergers and acquisitions involving businesses, pharmaceutical and medical device products
- Early stage drug, device, vaccine, and biological product research development agreements
- Co-promotion and co-marketing agreements
- Manufacturing, supply and distribution agreements
- Business broker and venture capital investment transactions
- Grant agreements
- Pre-clinical research agreements

- Government contracts
- CRO services agreements
- Clinical trial agreements

Throughout his career both as a General Counsel and as a compliance consultant, Mr. Buthusiem has advised numerous companies and institutions, their executive management and Boards of Directors on corporate governance issues involving fiduciary duties, and conflicts of interest. In particular, Mr. Buthusiem has rendered such advice in connection with the sale of pharmaceutical products to current and former employees, and has also advised on similar situations while serving as a director on external Boards. In each case, through his advice Mr. Buthusiem has sought to ensure that any conflicts of interest, whether in the context of transactions or generally, were appropriately addressed and proper safeguards implemented and followed accordingly.

EDUCATION

J.D. University of Pennsylvania School of Law, 1985
Activities: Member of Jessup Moot Court, 1984-1985 (Captain of the 1985 Team)

B.A. Temple University, 1982 (*magna cum laude*)

AWARDS

Recipient of the Temple University 2003 Diamond Achievement Award

Delivered the 2004 Commencement Speech, Temple University College of Liberal Arts

EXTERNAL BOARDS

Chairman, Temple University Board of Visitors for the College of Liberal Arts

Member, Temple University President's Council

Chairman, Temple University Law School Advisory Board for the Center for Ethics and Compliance

EDITORIAL BOARDS

Editor, Compliance and Risk Management eJournal, Legal Scholarship Network

Editor, the Lifesciences Compliance Update

EMPLOYMENT HISTORY

Temple University Beasley School of Law
Adjunct Professor
August 2015 – Present

Berkeley Research Group, LLC
Managing Director
January 2013 – Present

Kavo Kerr Group, a Danaher Company
General Counsel, Head of Business Development, Trade Operations and Environmental Health & Safety
November 2010 – January 2013

GlaxoSmithKline plc (formerly SmithKline Beecham plc)
October 1990 – October 2010

Senior Vice President and Special Counsel
January 2009 – October 2010

Senior Vice President, General Counsel of Global R&D and Vaccines Divisions, Business Development (Vaccines) and Risk Management
January 2001 – January 2009

Vice President & Associate General Counsel, Strategic & Scientific Transactions Department
January 1995 – January 2001

Senior Counsel, Licensing and Commercial Transactions
October 1990 – December 1995

Dickstein, Shapiro & Morin
Associate
January 1987 – October 1990

Fried, Frank, Harris, Shriver & Jacobson
Associate
September 1985 – December 1987

OVERSIGHT POSITIONS AND SPECIAL PROJECTS

Monitorships:

- Appointed by the FTC as a Monitor to review and periodically report on compliance with mandates contained in two Decisions and Orders issued by the FTC, each requiring the divestiture of multiple products, plants, and other tangible and intangible assets in connection with the approval by the FTC of 2 global mergers in the Lifesciences industry.

- Appointed by the DOJ and OIG to act as IRO for the largest Imaging Service Provider in Texas in connection with their CIA. As part of this process, was asked to assess the overall effectiveness of the company's compliance program in conformity with applicable State and Federal regulations, including the OIG Seven Elements. Was also required to test the company's billing and coding policies and procedures and to conduct a statistically relevant sampling of claims submitted for

reimbursement under State and Federal health plans to ensure that licensed physicians were present at and provided direct supervision on all imaging tests conducted with contrast dye in compliance with CMS regulations.

- Appointed by the DOJ/OIG to act as IRO for an acute care hospital in the mid-Atlantic region in conjunction with its CIA. The CIA addressed issues related to the coding of outpatient medical records, billing for ambulance claims, and submission of claims to the appropriate payor. Additionally, the CIA referred to internal procedures utilized by the system to review bills and claims submitted to payers for reimbursement. As set forth in the CIA, produced annual reports that detailed the accuracy of the statistically-valid sample selections for each category and an assessment of the internal control processes surrounding billing controls.

- Served as a court-appointed monitor for a large international mining company in connection with a consent decree related to violations of the Foreign Corrupt Practices Act. As part of the process, was asked to assess the entity's supply chains and ensure that sufficient internal controls were put in place to prevent and detect bribes to government officials overseas.

- Appointed by the DOJ/OIG to act as IRO for one of the largest national Durable Medical Equipment companies in conjunction with their CIA. Was further engaged to perform IRO services related to Non-Contractual Arrangements, which included a review of the internal system tracking mechanisms and recording of expenditures by physicians to ensure compliance with their Stark and Anti-Kickback policies.

Licensing Deals:

- Drafted, negotiated and completed numerous product and technology in-licensing and out-licensing and collaborative R&D ventures in the Biotech, Medical Device and Pharmaceutical industries.

Special Projects:

- Structured and negotiated a joint venture with the Chinese Academy of Science to form GSK's R&D Institute for Neurodegenerative Diseases in Shanghai, China.

- Formed and led a crisis management team for Danaher responding to a New York Times front page article linking its Cone Beam CT scanner to radiation overexposure in children. Issues involved FDA regulatory, congressional interaction, legal risk mitigation and media and communication management.

- Successfully represented Danaher Corporation's Dental Division in connection with criminal investigations involving alleged bribery and corruption in Russia and in the EU.

- Was responsible for establishing the CIA and IRO processes for GSK in connection with 2 DOJ settlements involving off-label promotion and falsification of cGMP data at its Ciera, Puerto Rico manufacturing facility.

- Negotiated a settlement with the NY AG in connection with Paxil consumer fraud relating to data falsification. As part of this settlement, was responsible for submitting all quarterly reports under the Consent Decree as well as interacting with the IRO appointed to oversee this matter.

- Formed and led the GSK crisis management team on pandemic vaccines, which managed all aspects of responding to the pandemic vaccine crisis in 2010, including negotiations with NGOs, government agencies, legal risk mitigation, licensing and development. As part of this process

negotiated an indemnity from the U.S. government against product liability exposure as a result of the emergency approval of the pandemic vaccine in in vitro data.

- Was legal counsel to the GSK Avandia crisis management team responsible for preparing for and delivering GSK' Congressional testimony to the House Oversight Committee convened to investigate claims of Avandia liability associated with a Meta-Analysis published by Dr. Steve Nissen of the Cleveland Clinic which linked Avandia to elevated CV risk.

- Led GSK Legal's cost reduction and efficiency project that resulted in substantial improvements in the delivery of global legal services as well as a rationalization of external counsel management and utilization, which yielded over $60M in savings over 3 years. Implemented the same program at Danaher and yielded comparable results over a 2-year timeframe.

- Responsible for coordinating the antitrust approvals in connection with the merger of SmithKline Beecham and GlaxoWellcome, including the Federal Trade Commission and European Commission approvals. Led the settlement negotiations with the FTC and the EC which resulted in the FTC Consent Decree and the EC Mandate. As part of this process, was responsible for working with the FTC Monitor Trustee with respect to post-merger obligations. Also led the team that divested the various products mandated by the FTC and the EC to be sold as a pre-condition to approving the merger, most notable of which was the $1.1. Billion global sale of Kytril to Roche Pharmaceuticals and the $1.68 Billion global divestiture of Famvir to Novartis.

- Member of a special R&D 'Blue Ribbon' task force whose mandate is to develop a comprehensive political, socioeconomic and scientific strategy for developing life-saving medicines to combat third world diseases. The other three members of the task force are the head of drug discovery, the head of project management, and the head of business development.

Acquisitions and Divestitures:

- 1994 $2.3 Billion acquisition of Diversified Pharmaceutical Services from United HealthCare.

- 1995 $1.45 Billion divestiture of SmithKline Beecham's Animal Health Business to Pfizer.

- 1995 $2.2 Billion acquisition of Sterling HealthCare from Kodak and related $1 Billion spin-off of North American part of the business to Bayer AG.

- Represented Belgium-based SmithKline Beecham ("SB") Biologicals SA in connection with its bid on the vaccine business of German-based Behringwerke AG division of Hoechst AG.

- Represented SB in connection with 1998 merger discussions with American Home Products and Glaxo Wellcome. In this capacity, was directly involved in strategic planning, substantive negotiations, legal due diligence and antitrust analysis.

- Represented SB in connection with the divestiture of SB's clinical laboratories business to Quest Diagnostics for $1.3 Billion; and SB's pharmaceutical benefits management business, Diversified Pharmaceutical Services, to Express Scripts for $700 million.

- Represented SB in connection with the 2001 $124 B merger with Glaxo Wellcome.

- Represented GSK in the FTC-mandated divestitures in connection with the GSK merger, including the $1.2 B sale of Kytril to Roche and the $1.4 B sale of Famvir to Novartis.

Joint Ventures:

- Drafted and negotiated a joint venture with Rite Aid Corp. and SB's Diversified Pharmaceutical Services division for the creation of a new company that will dispense prescription pharmaceuticals through use of mail.
- Newly formed UK joint venture Company with Holland-based Royal Gist brocades BV for the global production of certain penicillin bulk products.
- Represented Belgium-based SB Biologicals in formation of U.S. joint venture Company with, and related equity investment in, Microcarb Inc. relating to the worldwide development and commercialization of human bacterial vaccine products.
- Represented SB Consumer Healthcare in connection with restructuring of $2 Billion North American consumer healthcare partnership with Hoechst Marion Roussel.

Marketing Alliances:

- Completed a series of worldwide country-specific marketing arrangements between SB and German-based Boehringer Mannheim AG for the global commercialization and marketing of the cardiovascular drug carvedilol.
- Various U.S. Co-Promotion Agreements: with Janssen relating to Paxil and Risperdal; with Merck relating to Zocor; with Schering-Plough relating to a number of pipeline products; with TheraTech relating to Androderm; with Bayer relating to Baycol. Drafted and negotiated numerous marketing alliances for Danaher's MedTech business involving a variety of medical device products throughout the world.

RECENT TESTIMONY EXPERIENCE

Case No. 13-md-2460
In Re Niaspan Antitrust Litigation
United States District Court for Eastern District of Pennsylvania

Case No. 3:16-cv-0132
SEC v. Edward J. Kosinski
United States District Court for the District of Connecticut

Case No. 1:10-cv-03864
Jones et al. v. Pfizer, Inc. et al
United States District Court for the Southern District New York

Case No. 111CV203554
Glenridge Pharmaceuticals LLC. v. Questcor Pharmaceuticals, Inc.
Superior Court of the State of California for the County of Santa Clara
.
Docket Number 650908/14
Sybron Canada Holdings, Inc. v. Niznick,
Supreme Court, New York County

Case No. 1:13-cv-01475

Thermo Fisher Scientific, Inc. v. OpenGate Capital Group LLC
United States District Court for the District of Delaware

Case No. 8:12-cv-01623
In re: Questcor Securities Litigation
United States District Court for the Central District of California

Case No. 1:14-cv-20050-MGC
Direct General Insurance Co. v. Indian Harbor Insurance Co. et al.
United States District Court for the Southern District of Florida, Miami Division

Consolidated Case No. 1:14-cv-03547-RMB-KMW
AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc. et al.
United States District Court for the District of New Jersey

Case No. 16 Civ. 3241 (ER) (JLC)
Impax Laboratories, Inc. v. Turing Pharmaceuticals AG
United States District Court for the Southern District of New York

AAA Case No. 01-15-0006-0746
Torreya Partners LLC v. Mimetogen Pharmaceuticals, Inc.
American Arbitrators Association

Claim No. HC 2015 003978
Norgine B.V. v. Salix Pharmaceuticals, Inc.
High Court of Justice, Chancery Division (UK)

PUBLICATIONS

1. "Using Data Analytics and Enhanced Monitoring Techniques to Avoid Government Enforcement and Individual Liability," *Pharmaceutical Compliance Monitor,* July 16, 2015
2. "Drug Serialization Trends and Developments," *Pharmaceutical Compliance Monitor,* May 6, 2015
3. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* March 2015
4. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* February 2015
5. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* January 2015
6. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* December 2014
7. "Regulatory and Compliance Implications of Orphan Drugs," *Pharmaceutical Compliance Monitor,* November 24, 2014
8. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,*

November 10, 2014

9. "Recent Trends in Whistleblower Protection under Dodd–Frank," *Pharmaceutical Compliance Monitor,* October 20, 2014
10. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* October 2014
11. "Global Investigations and Compliance Services Enforcement Roundup," *BRG Newsletter,* September 2014
12. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* August 2014
13. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* July 2014
14. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* May 2014
15. "Global Investigations and Compliance Services Enforcement Roundup," *BRG newsletter,* April 2014
16. "Compliance Officers: Three Common Mistakes to Avoid," *Pharmaceutical Compliance Monitor,* March 19, 2014
17. "Six Strategies to an Effective Risk Assessment and Mitigation Program," *Pharmaceutical Compliance Monitor,* January 8, 2014
18. "Here Comes le Soleil Français: The French Sunshine Act Has Arrived," *Corporate Compliance Insights,* July 3, 2013
19. "PODs: Proceed with Extreme Caution," *Orthoworld,* June 10, 2013
20. "Five Steps to Sunshine: Strategies for Complying with CMS' Reporting Requirements," *Orthoworld,* May 9, 2013
21. "A Practical Guide to Anti-Corruption Compliance for the Medical Device Industry," *Pharmaceutical Compliance Monitor,* April 19, 2013
22. "Here Comes the Sun," *Pharmaceutical Compliance Monitor,* March 18, 2013

SEMINARS AND SPEAKING ENGAGEMENTS

Sixth Annual West Coast Compliance Congress

November 15 – 16, 2016

Current Trends in Compliance and Enforcement
April 7, 2016

Pharmaceutical Compliance Congress
January 26 – 27, 2016

Current Trends in Ethics and Compliance Law
November 9, 2015

DTA Business Essentials: Determining Fair Market Value for the Dental Industry
August 4, 2015

Pharmaceutical Compliance Congress
March 3 – 4, 2015

Fifth Annual West Coast Compliance Congress
November 13 – 14, 2014

Forum on Transparency and Aggregate Spend
August 18, 2014

FMV of HCP and Investigator Payments
May 20 – 21, 2014

Instruments Compliance and Ethics Synergy Conference
April 14, 2014

Sunshine Act 3.0
March 20, 2014

10th Annual Regulatory and Compliance Congress for Medical Device and Diagnostics
February 25 – 26, 2014

Latin America Compliance Conference
February 11 – 13, 2014

11th Annual Pharmaceutical Compliance Congress
January 28 – 29, 2014

Forum on Sunshine and Aggregate Spend
August 19 – 21, 2013

Here Comes the Sun
February 28, 2013

EXHIBIT 2

MATERIALS CONSIDERED

Filings

County of Cuyahoga, OH's Second Am. Corrected Compl., *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (N.D. Ohio May 30, 2018).

County of Summit, OH's Corrected Second Am. Compl. & Jury Demand, *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (N.D. Ohio May 29, 2018).

Expert Reports

Expert Analysis of Lacey R. Keller and supporting materials.

Produced Materials

Letter from K. Harper, Mallinckrodt to U.S. Dep't of Justice, Drug Enforcement Admin. (Nov. 1, 2010) [MNK-T1_0000280621–23].

Mallinckrodt Chargeback Transactions (1998 to 2017) [MNK-T1_0007965587–88].

Mallinckrodt Direct Sales Transactions (1998 to 2017) [MNK-TI_0007897646].

External Materials

CONG. BUDGET OFFICE, PRESCRIPTION DRUG PRICING IN THE PRIVATE SECTOR (2007).

Hui Zhao et al., *Fee-for-Service Contracts in Pharmaceutical Distribution Supply Chains: Design, Analysis, and Management*, 14 J. MFG. & SERV. OPERATIONS MGMT. 685 (2012).

Kathleen Iacocca & Yao Zhao, *Resell vs. Direct Models: US Branded Drug Distribution in the Future*, PHARMEXEC (July 17, 2015), *available at* http://www.pharmexec.com/resell-vs-direct-models-us-branded-drug-distribution-future.

Leroy B. Schwartz & Hui Zhao, *The Unexpected Impact of Information Sharing on US Pharmaceutical Supply Chains*, 41 INFORMS 354 (2011).

EXHIBIT 3: EXAMPLE DATA RECORDS – MALLINCKRODT DIRECT SALES DATA

Data Field Name	Example Record 1	Example Record 2	Example Record 3
Order_Company	00157	00157	00157
Order_Number	51872714	28532008	70184643
Order_Type	SO	SO	SZ
Line_Number	4000	3000	2000
Business_Unit	PDS0200	PDS0200	PDS0200
Sold_to_Address_Number	50009853	50045223	50005257
Sold_to_Alpha_Name	CARDINAL HEALTH	MCKESSON CORPORATION	AMERISOURCEBERGEN CORPORATION
Sold_to_Category_Code	003	003	003
Sold_to_Description	Indirect	Indirect	Indirect
Sold_to_Zip	43218	61834	08086
Sold_to_City	COLUMBUS	DANVILLE	THOROFARE
Sold_to_County	FRANKLIN	VERMILION	GLOUCESTER
Sold_to_State	OH	IL	NJ
Sold_to_Country	US	US	US
Ship_to_Address_Number	52000394	52001528	52000292
Ship_to_Alpha_Name	CARDINAL HEALTH,GROVEPORT,OH	MCKESSON CORPORATION	AMERISOURCEBERGEN DRUG CORP
Ship_to_Category_Code	003	003	003
Ship_to_Description	Indirect	Indirect	Indirect
Ship_to_Zip	43125	84104	98032
Ship_to_City	GROVEPORT	SALT LAKE CITY	KENT
Ship_to_County	FRANKLIN	SALT LAKE	KING
Ship_to_State	OH	UT	WA
Ship_to_Country	US	US	US
Ship_to_DEA_Number	RC0314891	PM0023046	RA0290938
JDE_Item_Number	1706937	1705088	1705731
Alpha_Item_Number	831501	035805	051205
NDC_Item_Number	00406831501	00406035805	00406051205
Transaction_Unit_of_Measure	BT	BT	BT
Product_Description	MORPHINE SULFATE ER 15MG TABS	HYDROCODONE/APAP 7.5/500 TABS	OXY/APAP 5/325 TABLETS USP
Package_Description	BOTTLE OF 100	BOTTLE OF 500	BOTTLE OF 500
Invoice_Document_Number	574509	235065	14846962
Quantity_Ordered	1428.0000	66.0000	132.0000
Quantity_Shipped	1428.0000	66.0000	132.0000
Quantity_Canceled	0.0000	0.0000	0.0000
Unit_Price	59.88	53.32	24.85
Extended_Price	85508.64	3519.12	3280.20
JDE_Status_Code_Next	999	999	999
JDE_Status_Code_Last	620	620	600
Requested_Date_Code	105087	99314	110349
Requested_Date	2005-03-28	1999-11-10	2010-12-15
Ship_Date_Code	105087	99314	110356
Ship_Date	2005-03-28	1999-11-10	2010-12-22
Invoice_Date_Code	105087	99315	110356
Invoice_Date	2005-03-28	1999-11-11	2010-12-22
Invoice_Year	2005	1999	2010
Wholesaler_ID			
Wholesaler_Name			
Wholesaler_Postal_Code			
Wholesaler_City			
Wholesaler_County			
Wholesaler_State			
Wholesaler_Country			
Agreement_Nbr	NONE		NONE
Contract_Name			
Contract_Effective_Date	0	0	0
Contract_Expiration_Date	0	0	0
Sequence_Number	89687400	137660848	329178051
List_Price	[redacted]	53.3200	24.8500

EXHIBIT 4: EXAMPLE DATA RECORDS – MALLINCKRODT CHARGEBACK DATA

Data Field Name	Example Record 1	Example Record 2	Example Record 3
Order_Company	00157	00157	00157
Order_Number	10995972	29869180	35252071
Order_Type	SH	SH	SH
Line_Number	1	1	1
Business_Unit	PHARMCORP	PHARMCORP	PHARMCORP
Sold_to_Address_Number	52064923	52044898	52090950
Sold_to_Alpha_Name	FRED MEYER STORE 0172 RX,KENT,WA	GIANT EAGLE 4010,ERIE,PA	FRANWIN PHARMACY,MINEOLA,NY
Sold_to_Category_Code	010	010	010
Sold_to_Description	Retail	Retail	Retail
Sold_to_Zip	98031	16506	11501
Sold_to_City	KENT	ERIE	MINEOLA
Sold_to_County	KING	ERIE	NASSAU
Sold_to_State	WA	PA	NY
Sold_to_Country	US	US	US
Ship_to_Address_Number	52064923	52044898	52090950
Ship_to_Alpha_Name	FRED MEYER STORE 0172 RX,KENT,WA	GIANT EAGLE 4010,ERIE,PA	FRANWIN PHARMACY,MINEOLA,NY
Ship_to_Category_Code	010	010	010
Ship_to_Description	Retail	Retail	Retail
Ship_to_Zip	98031	16506	11501
Ship_to_City	KENT	ERIE	MINEOLA
Ship_to_County	KING	ERIE	NASSAU
Ship_to_State	WA	PA	NY
Ship_to_Country	US	US	US
Ship_to_DEA_Number	BR1632098	BG0206183	AI9065423
JDE_Item_Number	1706937	1705088	1705731
Alpha_Item_Number	831501	035805	051205
NDC_Item_Number	00406831501	00406035805	00406051205
Transaction_Unit_of_Measure	BT	BT	BT
Product_Description	MORPHINE SULFATE ER 15MG TABS	HYDROCODONE/APAP 7.5/500 TABS	OXY/APAP 5/325 TABLETS USP
Package_Description	BOTTLE OF 100	BOTTLE OF 500	BOTTLE OF 500
Invoice_Document_Number	16128640	1323348	0
Quantity_Ordered	2.0000	1.0000	1.0000
Quantity_Shipped	2.0000	1.0000	1.0000
Quantity_Canceled	0.0000	0.0000	0.0000
Unit_Price	29.17	29.42	18.39
Extended_Price	58.34	29.42	18.39
JDE_Status_Code_Next	999	999	999
JDE_Status_Code_Last	620	620	620
Requested_Date_Code	105108	99343	110360
Requested_Date	2005-04-18	1999-12-09	2010-12-26
Ship_Date_Code	0	0	0
Ship_Date	0001-01-01	0001-01-01	0001-01-01
Invoice_Date_Code	105103	99343	110360
Invoice_Date	2005-04-13	1999-12-09	2010-12-26
Invoice_Year	2005	1999	2010
Wholesaler_ID	50009853	50045223	00512620
Wholesaler_Name	CARDINAL HEALTH	MCKESSON CORPORATION	AMERISOURCEBERGEN DRUG CORP
Wholesaler_Postal_Code	43218	61834	18017
Wholesaler_City	COLUMBUS	DANVILLE	BETHLEHEM
Wholesaler_County	FRANKLIN	VERMILION	NORTHAMPTON
Wholesaler_State	OH	IL	PA
Wholesaler_Country	US	US	US
Agreement_Nbr	3703500099		0560100039
Contract_Name			
Contract_Effective_Date	0	0	0
Contract_Expiration_Date	0	0	0
Sequence_Number	106678401	139394156	329695621
List_Price	[redacted]	53.3200	24.8500
Chargeback_Amount	[redacted]	23.900000	6.460000

EXHIBIT 5

SUMMARY OF DIRECT SALES OF MALLINCKRODT OPIOIDS

	Shipped Package Quantity		
Invoice Year	Total Direct Sales	Direct Sales to Retail	Retail as % of Total
1998	2,449,214	938,346	38.3%
1999	3,822,104	1,749,852	45.8%
2000	4,636,038	1,872,786	40.4%
2001	7,548,252	3,746,886	49.6%
2002	10,430,972	5,383,590	51.6%
2003	14,388,350	6,776,316	47.1%
2004	19,170,983	8,346,863	43.5%
2005	24,275,974	10,499,370	43.3%
2006	27,450,742	11,306,652	41.2%
2007	30,462,056	10,599,054	34.8%
2008	35,968,896	11,145,684	31.0%
2009	40,848,575	11,427,354	28.0%
2010	38,180,918	10,085,184	26.4%
2011	39,712,840	10,788,432	27.2%
2012	37,574,304	11,190,798	29.8%
2013	37,790,427	11,340,972	30.0%
2014	29,943,555	7,750,386	25.9%
2015	33,738,991	8,043,654	23.8%
2016	30,134,205	7,717,134	25.6%
2017	29,643,213	7,503,744	25.3%
Total	**498,170,609**	**158,213,057**	**31.8%**

EXHIBIT 6

SUMMARY OF RETAIL CUSTOMER PURCHASES OF MALLINCKRODT OPIOIDS

	Shipped Package Quantity		
Invoice Year	Total Retail Purchases	Direct Retail Purchases	Direct as % of Total
1998	1,576,577	938,346	59.5%
1999	2,943,643	1,749,852	59.4%
2000	3,318,860	1,872,786	56.4%
2001	5,687,880	3,746,886	65.9%
2002	8,185,651	5,383,590	65.8%
2003	11,073,491	6,776,316	61.2%
2004	14,287,298	8,346,863	58.4%
2005	19,010,270	10,499,370	55.2%
2006	20,810,803	11,306,652	54.3%
2007	22,475,163	10,599,054	47.2%
2008	27,394,859	11,145,684	40.7%
2009	30,262,883	11,427,354	37.8%
2010	29,459,518	10,085,184	34.2%
2011	29,491,640	10,788,432	36.6%
2012	28,233,487	11,190,798	39.6%
2013	28,888,869	11,340,972	39.3%
2014	23,326,993	7,750,386	33.2%
2015	26,541,441	8,043,654	30.3%
2016	24,999,508	7,717,134	30.9%
2017	24,440,182	7,503,744	30.7%
Total	**382,409,016**	**158,213,057**	**41.4%**

EXHIBIT 7

SUMMARY OF WALGREENS PURCHASES OF MALLINCKRODT OPIOIDS

	Shipped Package Quantity		
Invoice Year	Total Purchases	Direct Purchases	Direct as % of Total
1998	2,800	0	0.0%
1999	10,809	5,616	52.0%
2000	16,319	12,480	76.5%
2001	12,133	3,972	32.7%
2002	334,443	323,472	96.7%
2003	816,232	805,812	98.7%
2004	1,404,707	1,383,900	98.5%
2005	2,742,767	2,654,418	96.8%
2006	3,495,013	3,378,276	96.7%
2007	1,008,897	930,690	92.2%
2008	656,681	527,664	80.4%
2009	915,872	678,636	74.1%
2010	852,222	735,396	86.3%
2011	1,595,747	1,540,104	96.5%
2012	2,124,270	1,936,932	91.2%
2013	1,594,236	366,432	23.0%
2014	931,353	0	0.0%
2015	825,827	0	0.0%
2016	1,243,172	0	0.0%
2017	1,223,474	0	0.0%
Total	**21,806,974**	**15,283,800**	**70.1%**

EXHIBIT 8

SUMMARY OF WALMART PURCHASES OF MALLINCKRODT OPIOIDS

	Shipped Package Quantity		
Invoice Year	Total Purchases	Direct Purchases	Direct as % of Total
1998	54,705	49,122	89.8%
1999	98,951	69,564	70.3%
2000	199,724	82,158	41.1%
2001	1,062,081	859,344	80.9%
2002	1,885,221	1,665,504	88.3%
2003	2,098,710	2,018,994	96.2%
2004	2,767,282	2,719,092	98.3%
2005	3,136,193	3,103,392	99.0%
2006	3,655,816	3,636,294	99.5%
2007	4,679,157	4,664,844	99.7%
2008	5,473,187	5,418,012	99.0%
2009	5,625,666	5,426,784	96.5%
2010	5,634,941	5,531,130	98.2%
2011	4,986,077	4,869,942	97.7%
2012	4,174,943	4,058,220	97.2%
2013	4,253,088	4,173,438	98.1%
2014	4,639,099	4,600,236	99.2%
2015	6,893,996	6,799,770	98.6%
2016	6,476,364	6,470,496	99.9%
2017	6,312,812	6,303,912	99.9%
Total	**74,108,013**	**72,520,248**	**97.9%**

EXHIBIT 9: EXTRACTS FROM MS. KELLER'S CODE

Step 1: *The data matching Ms. Keller performed to "trace" Mallinckrodt chargeback records to Mallinckrodt Peculiar Order records was executed consistently with methodology described in her report.*

```
DROP TABLE IF EXISTS #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking;

SELECT DISTINCT b.ship_to_alpha_name AS peculiar_ship_to_name,
                b.sold_to_alpha_name AS peculiar_sold_to_name,
                b.arcos_name AS peculiar_arcos_name,
                b.invoice_date AS peculiar_invoice_date,
                b.order_number AS peculiar_order_number,
                b.ndc_item_number AS peculiar_ndc_item_number,
                b.ship_to_address_number as peculiar_ship_to_address_number
INTO #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking
FROM #chargebacks_mallinckrodt_summahoga_buyers a
INNER JOIN #mallinckrodt_peculiar_arcos b
ON a.ndc_item_number = b.ndc_item_number
AND (a.invoice_date > CAST(b.invoice_date AS DATE)
     AND a.invoice_date <= CAST(b.invoice_date AS DATE) + 30)
AND a.wholesaler_id =  b.ship_to_address_number;
```

Step 2: *The data matching Ms. Keller performed to isolate Peculiar Order records related to the "traced" chargeback records from Step 1 above was executed incorrectly and inconsistently with the methodology described in her report.*

```
SELECT *
INTO confidential_mdl.mallinckrodt_peculiar_summahoga_distributors
FROM #mallinckrodt_peculiar_arcos
WHERE ship_to_alpha_name IN (SELECT DISTINCT peculiar_ship_to_name FROM #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking)
AND sold_to_alpha_name IN (SELECT DISTINCT peculiar_sold_to_name FROM #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking)
AND arcos_name IN (SELECT DISTINCT peculiar_arcos_name FROM #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking)
AND invoice_date IN (SELECT DISTINCT peculiar_invoice_date FROM #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking)
AND order_number IN (SELECT DISTINCT peculiar_order_number FROM #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking)
AND ndc_item_number IN (SELECT DISTINCT peculiar_ndc_item_number FROM #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking)
AND ship_to_address_number IN (SELECT DISTINCT peculiar_ship_to_address_number FROM #summahoga_mallinckrodt_peculiar_chargebacks_summahoga_buyers_30_day_checking)
```